EXHIBIT 513

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

VOLUME II

The continued videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on January 19, 2011, commencing at 9:03 a.m.

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I N D E X

(Reporter's Disclosure Statement attached to back of transcript.)

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E X H I B I T S

E X H I B I T S (Cont'd)

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63	Regulatory Procedures Manual, Chapter 4, Advisory Actions	370
69	UDL Laboratories Receiving Form dated 4/10/08	403
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THE VIDEOGRAPHER: Good morning. We're on record. It's 9:03 a.m. This is the deposition of James J. Farley in the United States District Court for the Southern District of West Virginia, Charleston Division, the Digitek Product Liability Litigation, MDL No. 1968.

It is Wednesday, January 19th, 2011. We are at Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, 31322.

Would the counsel present please introduce yourself for the record, please.

MR. KERENSKY: Mike Kerensky and Meghan Carter Johnson for the plaintiffs --

MR. MORIARTY: Matthew --

MR. KERENSKY: -- and also Don Ernst, who is on speakerphone.

MR. MORIARTY: Matthew Moriarty for the Actavis defendants.

MS. DONAHUE: I'm Alicia Donahue from Shook, Hardy & Bacon for the Mylan defendants and UDL Laboratories.

THE VIDEOGRAPHER: Thank you.

Madam court reporter, would you swear the witness, please.

JAMES J. FARLEY

having been first duly sworn testified as follows:

EXAMINATION

BY MR. MORIARTY:

Q Now, Mr. Farley, I know you've been through depositions before. So let's just go over the rules very quickly. If you don't understand my question for whatever reason, you tell me and I'll make it clear to you. Okay?

A Yes, sir.

Q And if you need to take a break for whatever reason let us know and we'll do that. Typically we break every hour, hour and a half anyway. Okay?

A Yes, sir.

Q And if you need to look at a document we'll either give you one or you can get it out of your own supply of documents that you've reviewed and brought with you. Okay?

A Yes.

Q All right. Have you been -- have you had your deposition taken in any other litigation since my colleague, Mr. Anderton, took your deposition in June of 2010?

A No, I have not.

Q Have you given any trial testimony since June of 2010?

A No, I have not.

Q Have you been sued as a plaintiff or defendant in any lawsuit?

A No, I have not.

Q All right. Since June 2010 have you met with any of the plaintiffs' lawyers in the Digitek litigation?

A Just last night, Meghan and Mike --

Q Okay.

A -- here. But other than e-mails and phone calls from Meghan in the past couple of weeks telling me that I would be called upon, no.

Q All right. So the only in-person meeting you've had with any plaintiffs' lawyers in the Digitek litigation was last night to prepare for today's deposition, correct?

A Yes.

Q All right. And other than Mike Kerensky and Meghan Johnson Carter was anyone present?

A No.

Q Did you take any notes of that meeting last night?

A Yes.

Q Do you have those notes with you?
A Yes.
Q Where are they?
A They're in my folder that I put on the chair.
Q Okay. Can I see those?
A Yes. I'll get up.
Q Sure. Don't forget to take your microphone off.
A Thanks for reminding me.
MR. MORIARTY: Don, can you hear?
MR. ERNST: Yes. Although, Matt, I'm going to call in and see if we can have a speakerphone brought down to the room. So that may happen in the next half hour. But you're fine now. Thank you. I appreciate it.
MS. CARTER: I've already talked to them. They'll have it here in 45 minutes.
MR. MORIARTY: Meghan talked to the management. They're bringing one.
BY MR. MORIARTY:
Q Okay. Can I see the notes that you took from the meeting yesterday?
A This is what Meghan drew to assure everyone that --

MR. KERENSKY: Go ahead.

A This is what Meghan drew to differentiate between the Little Falls and the Riverview facilities to make sure that the three of us all were on the same page, so to speak. And we were.

Q Okay. Can I tear this off the tablet, the rest of which seems to be blank?

A Yes, sir.

Q What other notes did you take?

A Here's a sheet. I wrote less than a mile apart when Meghan and Mike were on speaker talking to a gentleman about the difference between Little Falls and the Riverview facilities. I wrote less than a mile apart.

Q Okay.

A And then later on in the evening Mike told me his phone number in case I needed to reach him.

Q Do you know who the other gentleman on the phone was?

A I was introduced to him and I don't remember his name. I'm sorry.

Q Was it Mr. Ernst from California?

A I don't know. I would have to ask Mike for that. I should know. I just don't remember his name. I didn't take any notes.

Q Did you take any other notes?
A Tucker, Ellis.
Q Important to know who am, I guess. You've handed me another sheet that says EIR, July 10th, 2006, Exhibit 90. Review the 483s and EIR. Put in --
A Chronological.
Q -- chronological order.
A Chronological order.
Q Anything else?
A These are notes I made to myself. I don't even know whose phone number that is at the top. But they're little notes I made to myself that don't seem to be connected even to me at this moment.
Q Okay. So the phone number at the top of this page of notes is 805-441-0988. Have you talked to any lawyers from California regarding the Digitek litigation?
A No, I have not.
Q What does the shoddy, S-H-O-D-D-Y, refer to?
A I believe to put it in the context we were talking about my opinion of Actavis and I was making my notes. I was not yet speaking, but I wrote shoddy. And then when Meghan and Mike finished and looked my way I used that term. Something like that.

Q All right. Do you have any other notes from the meeting?

A No, sir.

Q All right. How much time have you spent reviewing materials and talking to lawyers since your last deposition in June of 2010?

A Since then -- I heard the question. I'm pausing to try to give you an accurate answer. 24 hours last week and whatever time we spent here yesterday.

Q Okay. So essentially you did almost no work on Digitek between your last deposition and last week, correct?

A Correct.

Q All right. And you spent 24 hours last week, right?

A Yes.

Q What are you charging me and my law firm for the time we spend today in this deposition?

A I don't know the answer to that and the reason I don't is because I'm doing this for Smart Consulting Group, which is Dr. Nigel Smart and his wife, Denise Smart. They're doing the billing. I know they're paying me 150 dollars an hour. I really don't know what they bill any attorneys.

Q Do you know what the total amount to date

that you have been paid on the Digitek litigation including 2009, 2010 and this year?

A Around 36,000 dollars, give or take 3,000 on that.

Q Okay. Now, since your last deposition have you reviewed additional materials? I don't want to talk about the re-review of old materials. I want to talk about new materials.

A I'm pausing to give you an accurate answer. No, sir.

Q So we took the depositions -- the same week that you were deposed here we took the depositions of Karen Frank, Russ Soma and Mark Kinney in Philadelphia and New Jersey respectively.

Have you read any of their deposition testimony?

A No.

Q Have you reviewed the reports of Soma, Kinney, Frank or Bliesner?

A No.

Q Have you seen the reports of any defense experts in this case?

A No.

Q Some names would be Ron Snee, Lou M. Sell, Martha Bennett. Those would be three examples. Have

you seen their reports?

A None of them. I haven't heard of them.

Q Have you requested any additional materials since June 2010?

A No.

Q All right. Let's go into a couple of background things that weren't covered the last time.

A Yes.

Q Have you updated your resume' since June 2010?

A No.

Q And remind me where you went to college.

A My primary degree is from La Salle College in Philadelphia. It's now La Salle University. And then my master's degree in physical chemistry was at St. Joseph's College, which is now St. Joseph's University. And my MBA in marketing and finance was at Temple University.

Q And St. Joseph's and Temple are the ones in Philadelphia?

A Oh, all my schools were in Philadelphia. Yes, sir.

Q Are you a member of any societies or professional associations?

A The American Chemical Society.

Q Is that it?

A I'm thinking. One other organization is called AOPA. It's Aircraft Owners and Pilots Association. And it's a rather well-known organization for pilots.

Q All right. But as far as your profession, it's really the American Chemical Society?

A Just the American Chemical Society.

Q And do you hold any certifications or licenses?

A No.

Q Do you have any special training in quality assurance as opposed to quality control?

A I'm thinking. Do I have special training in it. I've taught it, but within what I think of as special training, no.

Q Do you consider yourself an expert in quality assurance in the pharmaceutical industry?

A That's tough to answer yes or no because it lies within the definition of an expert. I believe I'm very knowledgeable about it. I have consulted people on it and I believe I have helped them in the consultation. I would have used the term expert, although there are various definitions of what an expert is.

Q Well, is your core expertise in quality control chemistry?

A It is -- it overlaps. It's like a Venn diagram. It's tough to pick one thing. It's analytical chemistry. It's physical chemistry. It's quality control, which is part of quality assurance.

It's most recently manufacturing in the last dozen years. I can't answer that directly yes or no. I hope that I -- with that little dissertation I put it in the proper perspective.

Q Do you have expertise in regulatory affairs?

A Yes.

Q So what year did you graduate from La Salle?

A 1957.

Q And did you go straight for your master's after that?

A I enrolled at St. Joseph's University at night and then since I had four years of ROTC my work time was interrupted with military. And after getting out of the Army I went back to what was then Smith, Kline and French and continued my studies at night at St. Joseph's, receiving my degree in 1961.

Q When were you in the Army?

A 1958.
Q Just the one year?
A Yes.
Q And what was your rank on discharge?
A Final discharge from Reserves was captain, but discharge from active duty was second lieutenant.
Q So once you finished the Army what was your employment for the first few years after?
A At what was then Smith, Kline and French Laboratories in Philadelphia.
Q What did you do for them?
A I was the research analytical chemist, developing analytical procedures for new compounds.
Q Did that involve validation of methods?
A That was before the GMPs came into play and validation was not a term that was used. In effect you did that, but you didn't say we'll validate it, because the GMPs came into play around 1964, '65, '66.
Q All right. And how long did you work at Smith, Kline?
A I'm pausing to give you accurate information. In 1961 I left to go to SKF, no connection to Smith, Kline and French. It's called The Ball Bearing Place, metals and lubricants. I simply wanted to see what else was around in the field.

Q In the field of chemistry?
A Yes.
Q So SKF was not a pharmaceutical company?
A Was not.
Q How long did you work there?
A Two years. And then while I liked what I did as a research chemist there, I decided I liked pharmaceuticals and wanted to get back to the pharmaceutical industry.
Q Where did you go?
A What was then Wyeth Laboratories.
Q What did you do for Wyeth?
A Senior analytical chemist, developing new methods that would be used for testing raw materials, compounds and submissions to the FDA.
Q And did you do validation when you were at Wyeth?
A I want to say I did, but it was still just coming into play. The term wasn't used as it is today. But the equivalent of a validation, making sure that this method will work for the intended use.
So I'm going to say yes, but at the same time say the term validation, it was verify, validate, make sure it's right. These are the terms that were used then.

Q For either Smith, Kline or Wyeth did you work in pharmacovigilance?
A No.
Q Did you work in regulatory affairs?
A No.
Q Did you work in quality assurance?
A Not directly.
Q All right.
A I interacted with them, but I was not in quality assurance. I was research.
Q How long did you work at Wyeth?
A Until 1966.
Q Then where did you go?
A The West Company, now called West Pharmaceutical Services.
Q How long did you work at West?
A Until 1982.
Q All right. Now, did you leave Smith, Kline voluntarily?
A Yes.
Q Did you leave SKF voluntarily?
A Yes.
Q Did you leave Wyeth voluntarily?
A Yes.
Q All right. What did you do for The West

Company?

A A variety of things. I started out supervising their quality control department. That was one of the reasons I left, because it was a supervisory position.

As the company grew, the department expanded and they did more research, I mentioned that we might have a separate research function since now I had quality control background and the research background. And they let me form a research and development group more officially than they had before.

Then -- and I'm a little vague on this because so many years. But I ended up as assistant director of laboratories as the company expanded and was involved in talking to the customers, all of whom were pharmaceutical firms who wanted to bring their products to the market, because they bought the rubber stoppers from us.

And I interacted highly with various people, various firms that got more involved in the regulatory aspect in that our products, which were components of their final product, had to meet regulations.

Q All right. Did The West Company manufacture solid oral dose pharmaceuticals when you worked for them between '66 and '82?

A No.
Q Did you work on the manufacture of solid oral dose products when you were at Wyeth?
A Do you mean making them, putting them together --
Q Yes, sir.
A -- or if -- not putting them together. I analyzed them.
Q Okay. I'm asking whether you helped manufacture them.
A No.
Q Did you help in any way manufacturing when you were at Smith, Kline?
A In testing materials at points along the way to make sure a process was working well, but I myself was not in manufacturing.
Q All right. Did you go to the FDA in 1982?
A No.
Q Where did you go after The West Company?
A I formed my own training business.
Q What was it called?
A James Farley Seminars.
Q And how long did you run James Farley Seminars?
A That was off and on until 1987. I say off

and on. The business was on, but I realized at that point that I wasn't running my own business as well as I thought I could and I wanted to get back to the more steady income.

Q All right. So in 1987 did you go to the FDA?

A No, sir.

Q Where did you go in '87?

A Federal Government, Department of Defense in Philadelphia.

Q What did do you do for the Department of Defense?

A I was working with -- some parts were fabrics, but other parts were testing drugs that the Department of Defense would use. They were usually drugs beyond the expiration date that the DOD, Department of Defense, wanted to use for the military. And we would analyze them to verify that they were still good even though beyond expiration date.

Q Okay. So those years from '82 through -- how long were you with the Department of Defense?

A I was with the Department of Defense approximately one and a half years.

Q So sometime in '88 or '89?

A June of '89, to be precise.

Q All right. And so the years '82 when you were with West, you had your training business and then Department of Defense, you were not involved in the manufacture of solid oral dose pharmaceutical products?

A Not involved in the manufacture directly.

Q All right. And then what did you do in '89?

A I realized that while I now had steady income coming in, which is what I wanted, that I really wanted to get back to pharmaceuticals. And transferring from one federal organization to another was relatively easy. And the FDA was not even across town in Philadelphia. I applied there and they accepted me and I started working there.

Q Okay. So in your career have you ever done blend uniformity testing for solid oral dose?

A Testing?

Q Yeah, blend uniformity testing.

A I believe I have tested it; although I'm at a loss to say when and where.

Q Have you been involved in content uniformity testing of solid --

A Yes.

Q -- oral dose --

A Yeah.

Q Where?

A At Smith, Kline and at Wyeth. I'm trying to think, but definitely there.

Q When you were at -- when you did content uniformity testing did you use United States Pharmacopeia methods?

A I don't remember if we did or not. You don't have to use a USP method. You use the method that is most appropriate and is approved by the FDA. So while I don't remember which one, it could have been a USP method. It could have been a validated company method.

Q Would you agree with me that if a company is not going to use USP methods to test its pharmaceutical finished products, then it has to use a method validated and approved by the FDA?

A Yes, for materials that are to be released to the consumer.

Q All right. Did you have law and evidence training at FDA?

A Yes.

Q And I assume that was so you would have some understanding not only of what the regulations said but how FDA interpreted them; is that correct?

A Yes.

Q How many times did you actually go out on an inspection when you were with FDA?

A I'm trying to give you an accurate answer. I would say approximately quarterly.

Q Quarterly?

A Quarterly, which would be four times a year. Is that -- that's the best I can zero in on that.

Q All right. If I were to go back somehow and be able to study the records of FDA and look at warning letters and 483s from that period of time, how many would have your signature on them?

A One warning letter would have my signature on it. The 483s, I don't remember but I wouldn't be surprised if none of them did because the investigator's signature is on them. Oh, the analytical chemist does sign. Yes. There would -- a couple. I really don't want to mislead you or myself with a number.

Q The warning letter that would have your signature, if I recall correctly from your earlier testimony, is that the one you did not draft, you signed because somebody was out of the office that day?

A My boss was out and he said, you're in charge of the district the whole week. And a warning letter came in. That typically is signed by the district director.

And it is drafted by someone else, but it is a document that you, the person who signs it, read every word on and verify before doing it. So that's a -- is that a qualified yes?

Q I'm just asking if that's the instance.

A Yes.

Q Thank you. Have you ever done assay or content uniformity on Digoxin?

A I myself?

Q Yeah.

A No.

Q Have you supervised people doing assay or content uniformity on Digoxin?

A No.

Q Do you have any association whatever with assay or content uniformity on Digoxin?

A No.

Q When you did assay or content uniformity for any solid oral dose pharmaceutical product, did you ever use only single point UV testing?

A Would you tell me what you mean by single point UV?

Q Well, I'm not an analytical chemist, but I've had somebody tell me that that's how they analyzed a particular product. Okay? Not HPLC or any of those

things. They used the single point UV. Okay?

Do you know what that is?

A I would be speculating. If I could explain what is normally done -- would you like me to do that?

Q Nope. So you're not familiar with single point UV testing --

A If it's the single point -- oh, I'm sorry.

Q -- as the sole method for content uniformity of a pharmaceutical product?

A I know people have done single point UV. My personal opinion is you should do the complete scan and measure a couple of points to look for the shape of the curve to give you a better instance. So what I'm saying is I didn't do it -- excuse me -- because I don't feel that's the real accurate method.

Q It's not reliable, in other words?

A I would say you don't know the reliability of it and certainly the complete spectrum and taking readings at different points I believe would be more reliable.

Q Okay. In your -- in your -- in the last session of your deposition we marked an exhibit, 46. It was an article that you co-authored with a lawyer here in Savannah.

Do you remember that?

A With Gene Brooks?

Q Yes, sir.

A The article with Gene Brooks?

Q Yes.

A I co-authored that article with him.

Q All right. In that article you say that a laboratory must analyze the drug and test for its active pharmaceutical ingredient and for strength and purity. We'll get back to that in a little bit.

But it says here gas chromatography, liquid chromatography and microbiological tests are the three most common testing methods used for analysis, correct?

A Yes.

Q Single point UV is not one you would list, right?

A It's used but I probably would not list it. And I don't remember if I did or not there.

Q I read you the sentence. Do you want to see your own article?

A Yes, please.

Q Right there where the highlighting is.

A I read the highlighted part.

Q Okay. And single point UV is not a test method that you listed in your article, right?

A Correct, it is not what I listed in our article.

Q Okay. Now, is it now universally accepted that a method used in forensic work has to undergo validation?

A All methods have to undergo validation.

Q All right. So when you were actively doing chemistry, analytical chemistry, how many times did you run a method before you considered it validated?

A Validation of a method is not just a matter of how many times you run it.

Q I understand that. But overall how many times do you think you went through the process before you and your company considered it validated?

A Assuming the results came out as anticipated, a rule of thumb number is three. But that could be more or less, because there are -- there's a retrospective validation. There's other things we could bring in. But just keeping my question confined to what I'm considering now our area, rule of thumb would be three.

Q All right. So let me make sure I understand. Let's assume you in your work as a chemist are going to perform an analysis on a product that you've never analyzed before, ever, okay, and you're

going to start to figure out how to analyze this. So you're going to create the method and you're going to run the method and you're going to validate it from scratch essentially. Okay?

How long in terms of time, in hours, days, weeks, months, would that typically take?

A I have to ask you a couple of questions before I answer that.

Q Well, I'll let you even though it's my job to ask. But go ahead.

A In order for the purpose of accuracy, we're talking about a chemical method, not a microbiological?

Q Chemical method on solid oral dose pharmaceutical products.

A A completed product like a tablet --

Q Yes.

A -- that has the active pharmaceutical ingredient?

Q Yes.

A And the excipients in it?

Q Yes.

A How long would it take me to validate it?

Q Yeah.

A If you're working straight through on

nothing else, it could range anywhere from two days to two weeks.

Q Okay. So if I told you that a lab ran content testing on a solid oral dose product, in the total time from scratch through validation, running the standards, running the blanks and the ultimate sample took a total of two hours, that would be inconsistent with your experience, wouldn't it?

A To validate the method?

Q To start from scratch --

A From scratch.

Q -- on a product that they had never tested before, to create the method, validate it, run the standards, run blanks and run a sample for forensic reporting purposes, total of two hours, that would be inconsistent with your experience, wouldn't it?

A I would use the word inconsistent as opposed to impossible, inconsistent, surprising.

Q Okay.

MR. MORIARTY: Don, did you say something?

MR. ERNST: Yeah, I did. I thought it was a compound question.

MR. MORIARTY: Okay.

MR. ERNST: I objected.

MR. MORIARTY: Okay.

BY MR. MORIARTY:

Q In your work either at FDA or a pharmaceutical company did you use the Regulatory and Procedures Manual in the FDA?

A Yes.

Q Did you use the Investigation Operations Manual?

A Yes.

Q In your opinions in this case are you relying on FDA Form 483s?

A Among other things, yes.

Q And some of those other things would be warning letters?

A Warning letters.

Q And EIRs?

A That's Establishment Inspection Report, yes.

Q And so when you are looking at those FDA documents you believe they're reliable?

A Yes.

Q And how often do you look at the FDA's Web site?

A I go to the FDA's Web site a couple times a week for different purposes each time.

Q All right. Do you consider it reliable?

A Most of the time. I've seen cases where I believe it hasn't been.

Q Can you identify any instances where you question the reliability of the FDA's Web site so far as it applies to this litigation?

A Could you give me that question again?

MR. MORIARTY: Can you read it back, Angela, please?

(The record was read back as requested.)

THE WITNESS: Not that I saw on the Web site, no.

BY MR. MORIARTY:

Q Okay. Do you have any teaching duties now?

A Now? No.

Q When was the last time you had teaching responsibilities?

A The year 2000 in the Philadelphia area.

Q Doing what?

A I was teaching in the Graduate School of Pharmacy at Temple University, teaching -- excuse me -- process validation and another course was NDA submissions. I believe I was also teaching at a Penn State Philadelphia area campus management.

Q Okay. In your career as a consultant have you ever consulted for Actavis, Mylan, UDL or Amide?

A No.

Q Do you know the difference between possibility and probability?

A I believe I do.

Q All right. Probability would be more likely than not?

A Yes.

Q Possibility would be speculation, generally less than 50 percent chance of occurring?

A I haven't equated possibility with the word speculation, but I agree with the probability.

Q Okay. Now, before you drafted your original report in this case, which I believe was Exhibit 45 -- I'd have to make sure; hang on a second here -- yeah, Exhibit 45, I assume you read all of the material that had been supplied to you, correct?

A Yes.

Q And at that point did you know that the purpose of the report was essentially to put lawyers like me for the pharmaceutical defendants on notice of what your opinions were so that we had some idea what you were going to say when we came and questioned you?

A My answer is yes, but I would word it as

the purpose of the report was to render my opinion for anyone who cared to read it.

Q All right. And when was the last time you read your original report?

A Last week.

Q All right. And would you agree with me that nowhere in your original report, Exhibit 45, do you say that Digitek was in fact defective?

A I did not use those words.

Q All right. Now, this article, Exhibit 46, what was your role in writing this article as opposed to Mr. Brooks' role?

A I would like to take a minute to go back in the relationship. Gene Brooks is a person that we met on a vacation here in Savannah and he sort of clued us in on Savannah when we said we might consider moving here, it's a nice place.

And then Gene -- when we moved here Gene became a friend. And we meet periodically for lunch. Just talk about Savannah. And I don't even remember which one of us, but one of us at one time said, you know, we ought to put an article in some journal, let's get together and write something.

Whether he's the one that said with your background, Jim, and my law or whether I said with your

law and my background, I really don't remember. But we thought it would be a nice article to publish.

And (ck0 Jim Shepherd, he had just passed the Bar right around that time. So it's -- that was how that evolved, so to speak. That's the best answer I can give you on that.

Q Well, that gives me the evolution. But what was your role in the writing? I'm sure you two sat down and said you're going to do X and you're going to do Y. What was your role?

A In effect, Gene, you do the law stuff, Jim Farley, you do the pharmaceutical stuff.

Q Okay. So the statement, A laboratory must analyze the drug and test for its active pharmaceutical ingredient and for strength and purity, is that a statement that you wrote or that Gene Brooks wrote?

A I don't remember offhand, but it might have been Gene put it together and ran it by me and I might have agreed as is or modified it in some way. That's probably how it happened.

Q All right. So why did you or you and Gene say the laboratory must analyze the drug and test it for its API?

A So that you know that you have the proper drug. Am I answering your question properly?

Q Just answer it and I'll follow up. Why did you say that?

A Why did we say that?

Q A lab must analyze the drug and test it for its API and for strength and purity. Why?

A To be sure that it is what it is supposed to be.

Q Okay.

A Yeah.

Q So in other parts of this article you do talk about adulteration, correct?

A Yes.

Q So what you're advocating is to go beyond the regulatory definition of adulteration to testing to find out whether it is what it purports to be, correct?

A Yes.

Q Did you tell Mr. Brooks or did you contribute in any way to an analysis of the impact, if you will, or the meaning of GMP violations or recalls?

A In any way?

Q Yeah.

A We discussed it. I just am at a loss as to the exact nature of the conversation. But we discussed GMPs and what is a GMP violation. Yes, we did.

Q Okay. But did you discuss and did you contribute to writing about the actual impact, what does it mean when there is a GMP violation?

A I don't remember if we put that in there or not.

Q Do you consider yourself an expert on the legal ramifications of a violation of GMP?

A I'm not a lawyer. So I --

Q That's not what I asked.

A Well, that wasn't the whole sentence. It was I'm not a lawyer, therefore I don't consider myself an expert on legal ramifications.

Q All right. So when you were with these pharmaceutical companies in the years before you went to FDA, how much experience did you have with pharmaceutical recalls?

A Not much.

Q In your consulting work have you been asked to participate with your clients in working on recall issues?

A In some cases -- I'm pausing because I'm thinking of confidentiality.

Q I didn't ask for the name of a company.

A Okay.

Q I just right now I've asked --

A Yes, sir.
Q -- whether you've had experience in consulting with recalls.
A To a degree, yes.
Q All right. To your knowledge can FDA ask a pharmaceutical company to recall a product for virtually any reason?
A For virtually any reason? For -- I would say for a reason where they think there is potential for harm to the consumer. For any valid reason. I guess I'm getting a little tied up on that for any reason part of your question.
Q That's fine. That's fine. The FDA can ask a company to recall a product because of the potential for harm to consumers, correct?
A Yes.
Q They don't -- there does not have to be some proof before the recall that there's likely to be harm to consumers; is that right?
A Yes.
Q So in other words, neither FDA nor the pharmaceutical company have to come up with some proof that there is in fact out-of-specification and dangerous drug product in the marketplace and in the hands of consumers, right?

A Before I say right, you're saying proof and I would use the term they have a valid reason, somehow, somewhere they have a valid reason for asking for a recall, would you recall such and such from the market. It's a very expensive thing to do and it hurts the company's reputation.

So you use the word proof. I'm saying the FDA has a valid reason to believe there's a possibility or probability that a consumer or some consumers will be injured, harmed and they say, we want you to recall that. I had to extend that to put my answer in the proper context.

Q Okay. But you didn't answer my question.

MR. MORIARTY: Angela, can you read my question back, please?

(The record was read back as requested.)

MR. ERNST: I'm going to object. It's been asked and answered. He's answered the question. It's also compound.

A I --

Q Go on.

A I hear it again and it's still -- I'm getting -- the difference between proof and valid reason to believe that there's a probability that something can happen. And --

Q Let me ask it a different way. There doesn't have to be actual scientific evidence before a recall that there is likely out-of-specification and dangerous drug product in the marketplace, correct?

MR. ERNST: Objection, vague, ambiguous speculative. Those are not terms that -- you're making those terms. It's also compound.

MR. MORIARTY: And I'm going to just say that we don't have speaking objections in this MDL and those aren't PTO 22 objections. So if we're going to do this let's do it right.

BY MR. MORIARTY:

Q Can you answer my question?

A Could you tell me one more time, please?

MR. MORIARTY: You better read it back, Angela.

(The record was read back as requested.)

A Yes, correct.

Q Okay. Thank you.

MR. ERNST: Objection, vague, ambiguous.

Q Has any company that you either worked for or have consulted with been subject to a consent decree?

A Yes.

Q How about a seizure?

A No.

Q How about 483s?
A Yes.
Q Warning letters?
A Yes.
Q Recalls?
A Yes.
Q Have you seen any -- have you -- I'm sorry. Let me rephrase that.
Have you been provided with any scientific information whatsoever that there was a spike in Digoxin toxicity at hospitals, nursing homes, poison control centers or outpatient facilities in -- at any point between 2005 and 2008?
A I'm not sure what you mean by Digoxin toxicity.
Q Do you have any idea what that means?
A You mean OD, overdosing, or too much strength? I mean, Digoxin when used properly is not toxic. And to say Digoxin toxicity, if you mean over-strength tablets -- I'm not -- let me not put words -- please tell me again.
Q Digoxin toxicity simply for the purpose of my question is somebody who has a toxic reaction to Digoxin, whether the -- regardless of what the dose is. Okay?

What I'm asking you is whether you've been provided with any scientific proof that there was a spike in Digoxin toxicity at any sort of medical facility in the United States between 2005 and 2008.

A No.

MR. ERNST: I'm going to object, vague, ambiguous, calls for speculation.

MR. KERENSKY: When you get to a breaking point I'd like to take a break.

MR. ERNST: Scientific proof is not a standard.

MR. MORIARTY: Now is fine.

THE VIDEOGRAPHER: Okay. We're going off the --

MR. MORIARTY: Mike wants to take a break, Don. So we're going to do that.

THE VIDEOGRAPHER: Going off record. This is the end of Tape No. 1. 9:55.

(A brief recess was taken.)

THE VIDEOGRAPHER: Okay. We're back on record. It's 10:11 and this is the beginning of Media Unit No. 2.

BY MR. MORIARTY:

Q Mr. Farley, this is Exhibit 57 from your first deposition. This is a Form 483, is it not?

A May I? Yes.

Q Okay. And the Form 483 itself says, The document lists observations made by the FDA representatives during the inspection of your facility. They are inspectional observations and do not represent a final agency determination regarding your compliance.

Is that what it says right at the top of the document itself?

A It should. It's standard procedure.

Q Okay. And to your knowledge does the Regulatory Procedures Manual say essentially the same thing?

A As I recall, yes.

Q All right. So Exhibit 63, which is Chapter 4 of the Regulatory Procedures Manual, in Section 4-1-1 on the second page of this document, fourth full paragraph, A warning letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to take any enforcement action.

Did I read that correctly so far?

A Yes.

Q For these reasons FDA does not consider warning letters to be final agency action on which it can be sued.

Did I read that correctly?

A Yes.

Q Now, I want to ask you some questions about your report. Do you have a copy of it there?

A Yes.

Q All right. And that was Exhibit 45 in the last deposition, correct?

A If you say so. I don't remember the exhibit number of my report.

Q All right. Well, I have the original exhibits here if you need to look at them.

MS. CARTER: I think there was a 45A, B and C.

MR. MORIARTY: I think this was 45.

Q This one where it says, yes, 1 of 27. You got that in front of you?

A Yes.

Q Okay. Let's go to page 2 -- I'm sorry -- page 3. And when I say page 3, you've got these pages numbered, right?

A Yes.

Q So on page 3 the -- one, two -- third statement under your experience with FDA it's talking about your directing the activities of the 30-member lab staff, correct?

A Yes.
Q Now, did your work in that regard include processing 484 samples?
A Yes.
Q You know what 484 --
A Yes.
Q -- samples are, correct?
A Surveillance samples.
Q FDA collects samples from companies or pharmacy shelves and tests them, correct?
A Yes.
Q Using USP or comparable methods, correct?
A Yes.
Q And they're running things like assay and content uniformity on them, right?
A Yes.
Q And do they typically do surveillance samples on products that have narrow therapeutic indexes?
A Yes.
Q Do you know if Digitek is one such product?
A I do.
Q Do you know whether your lab in Philadelphia ever did 484 samples on any Digoxin

products when you were there?

A I don't remember.

Q All right. Let's go to page 4. At the very bottom the last sentence refers to ineffective or unsafe product. Do you see that?

A Yes, I do.

Q All right. First let's talk about ineffective product. What do you mean by that?

A A product that does not do what it is supposed to do would be an ineffective product.

Q So, for example, a product that had too little of the active pharmaceutical ingredient might be ineffective, right?

A Might be.

Q All right. And then what do you mean by unsafe product?

A I want to read the whole context. Can I do that?

Q Sure. I just want to know what you mean by unsafe product.

A Unsafe would be something that would do harm to the consumer.

Q Okay. So theoretically a product that had too much of its active pharmaceutical ingredient could potentially be harmful to a consumer, correct?

A That's one of the ways it could do harm to a consumer, yes.

Q All right. Let's go out to page 17. Now, under comments in Section 5 in Paragraph A you use the term "total failure" several times.

Do you see that?

A I see it.

Q To your knowledge was there ever a final agency determination by FDA that there was a total failure of quality systems at Actavis?

A Not using the terms total failure, but the consent decree told me that the FDA and the Court deemed they were incapable of making a quality product on their own.

Q What consent decree?

A The consent decree that Actavis received. I forget the date.

Q The one that ended in 2002?

A There was another one after that.

Q When?

A I'd have to look through.

Q What I'm asking is to your knowledge is there some final agency determination that says in these words that you've used here there was a total failure of Actavis' quality systems?

A Not the agency. The agency did not use that term.

Q All right. Now, is it your opinion that Actavis made no products in 2006, '7 or '8 that were within their specifications?

MR. ERNST: Object.

A I can't answer that if they made no products that were within their specifications. No. I would have to see the date on every single product they made in order to answer that.

Q Okay. Did FDA ever say in any document that there was a total failure of quality regarding Digitek?

A I did not see that from the FDA about Digitek.

Q Okay. Let's go to page 18. Go down to your Paragraph F on page 18.

A I'm there.

Q The end of your sentence says, All products, including Digitek, were adulterated. Do you see that?

A At the end.

Q Yes.

A Yes.

Q Can you show me a 483 or a warning letter

or any other FDA document that specifically says that Digitek was adulterated?

A That uses the term Digitek was adulterated?

Q Or something like that.

A I did not see it worded that way.

Q Okay. What was your understanding of why Digitek was recalled?

A My understanding was that there -- a combination of things. There were some adverse events reported from persons taking it. And upon FDA inspection some double thick or extra thick tablets were found. And at least one double thick tablet was found by a nurse or attendant person in a nursing home.

Q What is -- when was that -- well, let me break that down then in pieces. Okay? Let's get to the last thing you talked about first, this nursing home incident.

Was that tablet measured?

A Measured physically?

Q Yes.

A I believe but I am not sure. It went back to the company and they measured it and verified double thickness, but they did not analyze it.

Q What year was this?

A I forget offhand. I'd have to check the records.

Q Well, was it years before the recall or was it after the recall? Which the recall occurred in April of 2008.

A I believe it was before the recall.

Q You're talking about years before, the incident that was reported to the FDA, correct?

A I'm associating with 2006, but I'd have to go through the files to verify that date.

Q Well, let's just assume that it happened in 2005 or 2006. Did FDA order a recall when that occurred?

A Based on the one incident?

Q Yeah.

A No.

Q Did Actavis, or at the time Amide, report that incident to FDA in both a field alert and in its annual reporting?

A I believe they did.

Q And FDA was satisfied with the explanation given by Actavis in that it was an isolated incident, correct?

MR. ERNST: Objection to form.

A Yes.

Q All right. So can you show me a single document in all the documents that you reviewed to indicate that adverse event reporting had any influence on the Digitek recall?

MR. ERNST: Objection to form.

A In the 483s there's indicated that there's an inadequate adverse event reporting system at Actavis and that some events that should have been reported were not. So I would call that inadequate.

Q Didn't that happen in 2006 or 2007?

A Yes.

Q Didn't Actavis remediate that 483?

MR. ERNST: Objection to form.

A I don't believe it was satisfactory. They made some attempts, but they didn't do it well.

Q What does FDA do to a company when it is not satisfied with the remediation of a 483?

A They will go to a warning letter or they could just go to injunction procedure.

Q And if they -- if the company doesn't adequately remediate a warning letter what does the FDA do?

A They can -- they'll usually go to a consent -- they may go to a consent decree or they may shut them down.

Q Can you show me any evidence whatsoever that the FDA was not satisfied with the remediation of the adverse event reporting 483 that occurred in 2006 or 2007?

MR. ERNST: Objection to form.

A Could you repeat that, please?

Q Okay. You've got a whole pile of documents here that you reviewed to prepare your report and your opinions. Show me somewhere in all that material anywhere that you can that the FDA was dissatisfied with Amide's remediation or Actavis' remediation of the 483 regarding adverse event reporting.

MR. ERNST: Objection to form, compound.

A I see a series of 483s, then a warning letter, then a consent decree. To me that says they're not pleased with it. Otherwise they wouldn't have done that.

Q Okay. I'm talking about one issue, adverse event reporting, pharmacovigilance. Okay?

A Yes.

Q Not some mountain of events. I want to isolate AERs. Is there anything in the FDA's documentation in 2008 when Digitek was recalled that refers to adverse event reporting for Digitek?

MR. ERNST: Objection to form.

A That refers only to the adverse event reporting and not to not using the proper methods and not investigating deviations or out of spec, only the adverse event reporting?

Q Adverse reporting.

A No.

Q And can you find me any documents in all the material you reviewed to indicate that the FDA was not satisfied with the remediation of the adverse event reporting --

MR. ERNST: Same objection.

Q -- adverse event reporting 483 back in '06 or '07?

MR. ERNST: Objection to form.

A My indications was it was a combination of violations. But with regard to that one area, adverse event reporting, no, I did not.

Q Does the recall notice that was FDA approved say anything about adverse event reporting?

A No.

MR. MORIARTY: I happened to look at the transcript that is rolling up on the court reporter's computer screen and she has your name wrong, Don.

THE COURT REPORTING: No, I don't. I don't.

MR. MORIARTY: So we're going to correct that. Okay? I just want to make sure everybody knows. That should be Don Ernst, E-R-N-S-T.

THE COURT REPORTING: I know. That's coming up from the last deposition.

MR. MORIARTY: All right. And I'm not Mr. Anderton either.

THE COURT REPORTING: I know.

MR. ERNST: Thank you, Matt.

MR. MORIARTY: I was looking out for your interest, Don.

BY MR. MORIARTY:

Q Okay. Page 19 of your report, when a company is under consent decree don't they have to be in compliance with GMPs?

A You're asking me a question? You're not --

Q Well, at page 19 of your report under conclusions, Section 6, the fourth paragraph refers to the consent decree for ten consecutive years.

A Yes.

Q I assume you mean the one that expired in 2002, correct?

A Yes.
Q And I'm asking you a question about that. To be under consent decree with the FDA don't you have to be in compliance with GMPs?
A The consultants that are brought in assure that the product leaving the facility is in compliance.
Q So is that a yes?
MR. KERENSKY: Wait, wait. You can't do that.
Q Okay. You go ahead.
MR. KERENSKY: Thanks.
A I just want to make sure that I put this in the proper perspective. The material is in compliance because the consultants are there making it in compliance.
Q Okay. So in other words, for these ten years that you're referring to at page 19 of your report, Amide was within -- acting within the GMPs?
A In whatever areas the consultants were functioning in helping them to do so they were.
Q Okay. And ultimately when they came off consent decree in 2002 it was because of sustained compliance with GMPs, correct?
A It is when the Court decides that they are capable of making a quality product themselves, yes.

Q Let's go to the very end of page 19. Okay?

A Yes.

Q And you're talking about since the non-compliance problem was systemic all products, including Digitek, were adulterated as defined in Section 501 of the Food, Drug and Cosmetic Act.

Do you see that?

A Yes.

Q Okay. Is it your understanding that this litigation is about whether Digitek and other products at Actavis were considered adulterated under its regulatory definition?

A That's part of it. It's my understanding that there was a probability that some material produced by Digitek could harm a consumer.

Q Okay. Is there some statement in any FDA document that there is a probability that out-of-specification Digitek was shipped to the marketplace?

A Specifically as you worded that, no.

MR. ERNST: Objection to form.

Q To your knowledge did FDA say anywhere in a 483 or a warning letter that double thick tablets had in fact made it to the marketplace?

A In a 483?

Q Or a warning letter.

A Warning letter? No, they did not say it the way you just worded it.

Q Did the FDA anywhere in a 483 or warning letter say that out-of-specification Digitek tablets had made it to the marketplace or in the hands of consumers?

MR. ERNST: Objection to form.

A I'm pausing because they're not going to say that in a 483. The 483 is going to say what you're doing in the plant, the facility that's being inspected. It's not in the range of a 483 to say whether it's on the marketplace or not.

So that's why I'm looking surprised at the wording of the question, because the answer is not -- it's like, of course, not, it won't in a 483.

Q Okay. Were you aware that FDA in the latter half of 2006 asked Actavis to bring in a consultant for some batch record reviews?

A Yes.

Q And the purpose of that in essence was to see according to the batch record reviews whether products were being made in accordance with GMPs, correct?

A Currently or before?

Q At the time.
A The previous batch review or the current batch record review? Because they do both.
Q Whatever. That was what FDA wanted Actavis to do, correct?
A Yes.
Q All right. This is Exhibit 23. Have you ever seen this before?
A Yes. I think. Yes.
Q The top sheet is a letter December --
MR. ERNST: To clarify, when you say have you seen this before can you identify that for me.
MR. MORIARTY: Exhibit 23.
MR. ERNST: Thank you.
Q The top sheet is a letter dated December 24th, 2007, to FDA from Scott Talbot at Actavis, correct?
A Oh. Yes.
Q All right. And attached is reports from Quantic Regulatory Services, correct?
A Yes.
Q Do you know anything about the reputation of Quantic Regulatory Services?
A I have done work for Claudio Pincus, who owns Quantic. I've done work for --

MR. KERENSKY: That's not the question.

A So, yes. They have a very good reputation.

Q Have you -- when you had Exhibit 23 did you look through the attachments that actually came from Quantic Regulatory Services?

A Much was redacted. But, yes, I did.

Q And do you know that they looked at a number of Digitek batches?

A I'd have to go back to the text. Because of all the redactions I can't see what they did or didn't do. Oh. I see some Digitek.

Q Well, did you ever count how many Digitek batches there were?

A I probably did at that time and I'm at a loss to tell you what that number is at this moment.

Q Okay. If I told you that 19 of the batch records that they looked at were ultimately amongst the recalled batches, would you have any reason to dispute that?

A I would not have any reason to dispute that.

Q And I think they looked at a total of 23 Digitek batch records. Have you looked at any batch records of Digitek other than Batch 70924?

A Other than that batch, no.

Q It says on the first page of this exhibit in the letter from Mr. Talbot to FDA, On December 21st, 2007, Quantic provided Actavis with a statement indicating the audit was complete and the manufacturing and the lab records will reliably confirm the identity, strength, quality and purity of the marketed products.

Do you see that?

A I see it.

Q Do you have any basis to disagree with Quantic Regulatory Services' conclusions regarding the batch record -- or the batch records that they reviewed?

A In one sense I do not have any reason to disagree with what Quantic said and found. But based on what I read in the 483s about the way they were manufacturing, it is surprising to me.

Q Okay. Now, this phrase that they use in this sentence, reliably confirm identity, strength, quality and purity, that mirrors the definition contained in the Food, Drug and Cosmetic Act regarding adulteration, correct?

A Yes.

Q So if you were to assume that Quantic was correct in reliably confirming identity, strength, quality and purity of at least the batches they

reviewed, assuming they were correct, those wouldn't even be considered adulterated. Isn't that true?

A If they confirm identity, strength, quality and purity they are normally not considered adulterated.

Q I'm handing you what's been marked as Exhibit 24, do you recognize that as a Form 484 from FDA?

A I don't.

Q Have you ever seen that document before?

A I'm taking a look in here. I'm having trouble reading the top where it's dark.

Q Well, let's go slowly -- let's go slowly through it. Okay? It's Sample 377410, correct? Up here.

A Oh. Sample No. 377 -- I'm just having trouble reading it because of the Xerox copy of it. But you're reading right here where I'm pointing in the dark area?

Q I have my own notes.

A Oh, okay. For Sample No. 377410.

Q Okay. And in the document, if you look at the first page, on February 9th, 2007, FDA secured two bottles of hundred count .125 milligram Digitek from Actavis. Do you see that?

A I'm looking for -- I'm looking for where it says two bottles. It's either in small print or my eyes are getting weak.

Q I apologize. I used to have highlighted versions of these so I could point right to the part of this document that you need to see.

MR. KERENSKY: It's under description of sample two-thirds of the way down.

THE WITNESS: Thank you. I wasn't that far down. I was still way up here.

MR. KERENSKY: You want me to find it for you?

THE WITNESS: I see it now.

BY MR. MORIARTY:

Q Okay. And then in the middle in the same area where Mr. Kerensky just pointed out, you see manufacturing code? Right here.

A Yes.

Q That's Actavis Batch 70078A. Do you see that?

A Yes.

Q Okay. And you can look at this as thoroughly as you would like, but wouldn't I be correct in saying that after running thorough quality control chemistry testing on these tablets using USP methods,

FDA found them to be in compliance with their stated specifications?

A I'm looking to read this. I want to see where it says they used the USP method.

Q You take your time and look at the whole thing.

A Okay.

Q These are exhibits I've covered with other experts. If you doubt that I'm representing these to you accurately, you take all the time you want, because I've got about ten of these to go through.

A I'm not doubting your presentation. It's I want to make sure what I'm reading.

MR. KERENSKY: Let's take a little break.

MR. MORIARTY: We have 15 minutes on the tape and there's a pending question. As soon as he answers this question we can take a break.

MR. KERENSKY: Well, for the purpose of review I'm just saying let's stop the tape and just give him time. I'm not saying so I can talk to him. I'm saying let's go off the tape and see if we can find a sane way to go through that stack of documents.

MR. MORIARTY: That's fine.

MR. KERENSKY: Okay?

THE VIDEOGRAPHER: We're off record --

MR. MORIARTY: Oh, wait. Before we go off record -- you still on?

THE VIDEOGRAPHER: Yes, sir.

BY MR. MORIARTY:

Q I'm ultimately going to ask you about Exhibits 25, 26, 27, 28, 29, 30, 31, 32, 33 and 34. And I'm going to ask you essentially the same questions about --

A Yes.

Q -- all of them. Okay?

A Yes.

Q So if you want to look at all of them while we're on break I'll put the whole stack right here. Okay?

A Actually I forgot that question already.

MR. KERENSKY: The question -- are we still on record?

THE VIDEOGRAPHER: We are still on the record, yes.

MR. KERENSKY: The question as I understand that you want to ask is whether or not these documents show that the FDA tested the samples that they took and found them to be in compliance with their specifications.

Is that right?

MR. MORIARTY: Yes, sir.

MR. KERENSKY: Okay. All right. Let's go off the record.

THE VIDEOGRAPHER: We're off the record, 10:47 a.m.

(A brief recess was taken.)

THE VIDEOGRAPHER: All right. We're back on record. Back on record. It's 11:05 a.m.

MR. KERENSKY: We took a break. And we are stipulating for the purposes of this deposition that Exhibits 24 through 34 -- is that the range, is that the correct range --

MR. MORIARTY: Yes, sir.

MR. KERENSKY: -- represent testing done by the FDA on Digitek tablets wherein the FDA found that the Digitek tablets were within specification.

MR. MORIARTY: Okay.

MR. KERENSKY: Okay. So no need to go through each and every one. We're -- and you can -- he's going to assume that to be true and you can ask him questions from there.

MR. MORIARTY: Okay.

BY MR. MORIARTY:

Q From the two exhibits that you did review, which were 24 and 25, that is correct, isn't it --

A Yes.

Q -- that FDA did 484 sampling, tested them and they complied with the specs, correct?

A Yes.

Q All right. Now, when FDA runs tests under the 484 program they can test assay, content uniformity, dissolution and impurity, correct?

A Yes.

Q They may not necessarily run all those tests on every sample, right?

A Correct.

Q Okay. Have you ever seen a 484 sample from FDA of Digitek which found that the product was not within specifications?

A I did not.

Q Do you know if any exist?

A I do not.

Q Do you know if the plaintiffs' lawyers who retained you as an expert in this case ever ran a Freedom of Information Act request to find out that kind of information?

A I know that there were I believe 1,880 samples taken over a period of time. And my --

MR. KERENSKY: No, no. The question is whether or not you know if the lawyers representing the plaintiffs --

MR. ERNST: Objection, vague. Objection to form.

MR. KERENSKY: -- made a Freedom of Information Act -- listen to the question.

MR. MORIARTY: This is great. Don, you're objecting to your own side's question. I love it.

MR. KERENSKY: No. I'm just trying to help him.

He's asking you do you know did the lawyers make a Freedom of Information request, yes or no. That's what he asked you.

THE WITNESS: Is that what you asked me?

BY MR. MORIARTY:

Q Yes, that's what I asked you.

A That did the lawyers for the plaintiffs ever -- say again, please.

Q Do you know whether the lawyers for the plaintiffs, the lawyers who hired you as an expert in this case, made a Freedom of Information Act request to get 484 sampled?

A I do not know that.

Q Okay. So to the best of your knowledge FDA never found any out-of-spec Digitek in the field in its 484 program testing?

A To the best -- I don't know the answer. I don't know if they did or didn't. I believe that -- that's all for that answer.

Q Would it be important for you to know that?

A It would be important for me to know if they sampled a couple hundred thousand and found every one in specification. That would be important for me to know and to change the opinion that I have formed.

These samples don't tell me statistical representation that there is not a likelihood of harm from Digitek -- was not a likelihood of harm from Digitek out there.

Q Okay. Let's talk about scientific data available to you. Okay?

A Yes.

Q FDA is your former employer, correct?

A Yes.

Q You're relying on their 483s and their warning letters for your opinions in this case about adulteration, aren't you?

A Yes.

Q FDA chooses the sample size for their 484 program, don't they?

A Yes.

Q They can take as many samples as they want, couldn't they?

A Yes.

Q So do you have any data anywhere, any scientific data, that shows out-of-specification Digitek in the hands of pharmacists or consumers?

A I don't have scientific data. However, the purpose of a surveillance, also known as survey sample, is to take a sample not indicative of everything that was produced, but a sample to determine if that sample is good or not. It does not tell me that there isn't any harmful Digitek out there. All of this is small.

Q That's nice. What I'm asking you, Mr. Farley, what data do you have that there is in fact harmful out-of-specification Digitek out there in the hands of consumers? Okay? This is what I've got plus more.

A Yes.

Q What have you got?

A If you mean other than the 483s saying it was not made right, you mean analytical data showing

that something was double strength?

Q Let's start there. Do you have any analytical data?

A I do not have analytical data indicating that.

Q Do you have physical measurements from pharmacists or any reliable scientific person?

MR. ERNST: Objection to form.

A Of a tablet?

Q Of any tablets that were out of spec.

A What I read in here that there were at least 20 of them that were double thickness and they never analyzed them to see if they were double strength. But not from a pharmacist I contacted.

Q Did any of those 20 double strength tablets or double thick tablets, whatever you want to call them, even leave the Actavis facility?

A The one that was found by someone at a nursing home obviously did.

Q In 2006?

A I believe that's the year.

Q I'm asking about the 20 in Batch 70924. They were removed and destroyed, weren't they?

A They were, but it leads me to wonder how many weren't caught and got out to the consumer.

Q You can --

A It doesn't tell me it never happened, that nothing got out.

Q You can wonder about that. I'm asking for your data that it happened. Do you have any data?

A No concrete data that it happened.

Q All right. So of all the lawsuits and all the lawyers in the Digitek litigation, did any of them send you either a double thick tablet or a report that there was a double thick tablet?

MR. ERNST: Objection.

A The data that I received from Pete Miller and all the documents had contained in it the finding of the double thick tablets. So is that what you -- so my answer would be yes based on that.

Q Okay. I want you to go in the corner and get your material and I want you to find any piece of paper in there that says that there was a double thick tablet in the hands of a consumer in 2006, '7 or '8.

A No, not in the hands of a consumer.

Q How about in the hands of a pharmacist in 2006, '7 or '8, can you find a piece of paper that says that?

A I cannot find a -- I do not have a paper that says that.

Q Had you ever seen Exhibit 25 before?
A I believe not.
Q Had you ever seen Exhibit 26 before?
A I'd have to check my list of exhibits, but I believe I did not see these.
Q How about 27?
A And so on right through the list.
Q What about 27?
A No.
Q What about 28?
A No.
Q 29?
A No.
Q 30?
A No.
Q 31?
A No.
Q 32?
A No.
Q 33?
A No.
Q Or 34?
A No.
Q In your consultation work is this the kind of data that you rely on, these 484s, is this the kind

of data that you rely on in your consulting work?

A To do what?

Q To talk to your own clients.

A To advise them on how to make good material?

Q Okay. Let me go back, because my question was bad. Have you ever been consulted by a pharmaceutical company that the question posed to you was, do we have any out-of-specification product in the marketplace?

A In the marketplace?

Q Yeah.

A No, not worded that way.

Q Okay. If a client consulted you and wanted help from you in regard to figuring out whether there was out-of-specification product in the marketplace, okay --

A Yes.

Q -- is the 484 results something that would be important for you to look at?

A They would be part of the picture, not all.

Q Do you know who or what Celsis Laboratories is?

A Could you spell that, please?

Q I believe it's C-E-L-S-I-S.

A No, not offhand. It might be, but it's not ringing a bell offhand.

Q All right. Are you aware that Actavis sold all the Digitek it made to distributors, not directly to pharmacists, in other words?

A That's what is normally done. So it doesn't surprise me.

Q And do you know for a fact whether the distributors like Mylan or UDL commissioned any testing on the Digitek that it bought from Actavis?

A Do I know that they did? I know -- I would recommend that they should in any case from anybody. But whether they did, I am not sure offhand.

Q Okay. I'm going to hand you Exhibit 35. First of all, have you ever seen that document before?

A I have not.

Q Why don't you take a quick look through it. I'll represent to you that this document contains information on three Digitek batches made in 2006. These tests were commissioned by Mylan or UDL and the testing was done by Celsis Analytical Services. Okay?

A I see.

Q And I believe they did assay and dissolution testing on these three Digitek batches and

found them all to be within the specs. Okay? So take your time, take a look at that stuff if you'd like and tell me if I am incorrect in the way I've represented this exhibit to you.

A I hear what you said, but I'm just looking through it.

Q Have you had a chance to go through that?

A I'm glancing through some of it. I'm showing you how far I am. Do you want me to go through the whole thing?

Q All I want you to -- I mean, is that Celsis Labs results from testing three batches of Digitek and did they all conform with the specs? That's the question.

MR. KERENSKY: Object to the form of the question. They didn't test three batches. They tested three bottles, one bottle each from each batch.

Q Mr. Kerensky is correct.

A I heard two questions. Is there analytical data from Celsis Labs? Yes. Did they test three --

Q Three samples.

A Samples.

Q Or samples from three batches of Digitek.